REMARKS/ARGUMENTS

With this amendment, claims 53, 55-58 and 60-74 are pending. For convenience, the Examiner's rejections are addressed in the order presented in a December 1, 2004 Office Action.

I. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 53, 55-58 and 60-74 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. According to the Office Action, the specification lacks description of the claimed invention, such that a skilled artisan would recognize that Applicants had possession of the claimed invention at the time of filing. The claims are directed to cell-based methods of producing product saccharides by combining a heterologous accessory enzyme for forming a nucleotide sugar and a heterologous glycosyltransferase in the same cell; contacting the cell with an acceptor saccharide and allowing formation of the nucleotide sugar through activities including the activity of a heterologous accessory enzyme, followed by transfer of the sugar to the acceptor saccharide through the activity of the heterologous glycosyltransferase. Applicants respectfully traverse the rejection.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); and MPEP 2163. Possession can be demonstrated in a variety of ways. "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP 2163 *citing Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). As the Examiner has withdrawn rejections to indicate that the claims are enabled and free of art, possession of the invention at the time of filing is the sole remaining issue.

Possession is also addressed in the USPTO's Synopsis of Application of Written Description Guidelines, which acknowledges that when a process is claimed and the novelty of the process is in the method steps, description of particular nucleic acids used in the method is not required. Applicants direct the Examiner's attention to Example 18 of the Synopsis of Application of Written Description Guidelines which analyzes a claim directed to a method of producing a protein of interest in *Neurospora* mitochondria by transforming the mitochondria with a nucleic acid that encodes the protein of interest. No specific nucleic acid or amino acid sequence is found in the claim. In these Guidelines, the Patent Office concluded that the claim was adequately described within the meaning of 35 U.S.C. §112, first paragraph. In particular, note the Patent Office's rationale:

> A review of the specification reveals that *Neurospora crassa* mitochondrial gene expression is essential to the function/operation of the claimed invention. A particular nucleic acid is not essential to the claimed invention.
>
> A search of the prior art reveals that the claimed method of expression in *Neurospora crassa* is novel and unobvious. The claim is drawn to a genus, *i.e.*, any of a variety of methods that can be used for expressing protein in the mitochondria.
>
> There is actual reduction to practice of a single embodiment, *i.e.*, the expression of β-galactosidase.
>
> The art indicates that there is no substantial variation within the genus because there are a limited number of ways to practice the process steps of the claimed invention.
>
> The single embodiment is representative of the genus based on the disclosure of *Neurospora crassa* mitochondria as a gene expression system, considered along with the level of skill and knowledge in the gene expression art. One of skill in the art would recognize that applicant was in possession of all of the various expression methods necessary to practice the claimed invention.
>
> **Conclusion:**
> The claimed invention is adequately described.

The novelty of the claimed methods is in the methods steps. No particular heterologous glycosyltransferase or heterologous accessory enzyme is required to practice the invention. At the time of filing, all of the reaction components for the claimed methods were

known, including activities of accessory enzymes, activities of glycosyltransferases, and saccharide products of glycosyltransferases. However, it was not known that a single cell comprising both a heterologous accessory enzyme and a heterologous glycosyltransferase could be used to produce product saccharides in an efficient and low cost manner. Based on the disclosure of the specification, those of skill would be able to distinguish the claimed methods of saccharide production from other methods of saccharide production, *e.g.*, methods that do not employ cells comprising both a heterologous accessory enzyme and a heterologous glycosyltransferase. Once efficient production of product saccharides using a single cell comprising both a heterologous accessory enzyme and a heterologous glycosyltransferase were demonstrated, those of skill would have recognized that the methods were not restricted to a particular accessory enzyme or glycosyltransferase and that the inventors were in possession of the claimed invention.

The invention provides ample disclosure of the steps required to produce a product saccharide using host cells that comprise both a heterologous accessory enzyme and a heterologous glycosyltransferase, *i.e.*, the claimed methods. Applicants respectfully assert that analysis of the claims must be focused on the method steps. The steps of the claimed methods are straightforward: contact a host cell that comprises a heterologous accessory enzyme and a heterologous glycosyltransferase with an acceptor saccharide and allow formation of the nucleotide sugar using the activity of the accessory enzyme and then transfer of the sugar form the nucleotide sugar to the acceptor saccharide using the activity of the heterologous glycosyltransferase. The steps are described in the specification, *e.g.*, at page 43, lines 23 through page 46, line 26. Working examples are provided at page 59-61, Example 1; page 62, Example 3; page 63, Example 5 and Example 6; and page 63-64, Example 7. After review of this disclosure, one of skill in the art would recognize that the inventors were in possession of all of the methods necessary to practice the invention. Therefore, the claimed invention meets the written description requirement.

The claimed genus of methods is fully described in the specification, which includes recitation of a representative number of species for the accessory enzymes,

glycosyltransferases, and product saccharides used in the claimed methods. However, the Office Action appears to assert that the genera of glycosyltransferases, accessory enzymes, and product saccharides are not described in the specification. *See, e.g.*, Office Action at pages 2-3. The description of the method steps does not appear to be at issue, for example, enablement rejections have been withdrawn, indicating that the specification does teach how to use the claimed methods to make product saccharides. Rather, the Office Action appears to focus on the description of certain components used in the claimed methods.

The Office Action appears to assert that, in order to comply with the written description requirement, the description of accessory enzymes, glycosyltransferases, and product saccharides must comply with a description requirement for new or previously unknown genetic materials as set forth in *Regents of the University of California v. Eli Lilly* 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). This is incorrect. First, product saccharides are described by sugar structures (as are disclosed in the specification), were known at the time of filing, and are not genetic material, *i.e.*, a nucleic acid or amino acid sequences. Second, accessory enzymes and glycosyltransferases were well known at the time of filing and Applicants have assisted the user by listing a large number of those enzymes in the specification.

Moreover, even if *Lilly* is applied to the claims, accessory enzymes, glycosyltransferases, and product saccharides are adequately described in the specification and the description enables those of skill in the art to use the claimed methods. Furthermore, "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." 66 Fed. Reg. 1099, 1106 (2001), citations omitted. The page and line numbers of the specification that reference accessory enzymes, glycosyltransferases, and product saccharides were provided in previous responses mailed on July 20, 2004 and faxed on February 19, 2002. The Examiner is invited to review those previously submitted responses, if necessary, for the page and line numbers of the specification that reference accessory enzymes, glycosyltransferases, and product saccharides. Thus, the claimed invention is described in the specification.

In view of the above arguments, withdrawal of the rejections for alleged lack of written description is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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